APR - 2 2001

510(k) Summery of Safety and Effectiveness

ANTYLLOS® MEDIZINTECHNIK GMBH
Karpfenstr. 20, D-78532 Tuttlingen

K010192

Titel: Endoscopic Tube Shaft Instruments for monopolar Coagulation

December 20, 2000

Submitted by	Ing.-Büro Jung Unterer Winkel 3 D-78573 Wurmlingen
Contact Person	Harald Jung Telefon +49 7461-96 92 36 FAX +49 7461-96 92 37
Trade Name	Endoscopic Tube Shaft Instruments for monopolar Coagulation
Common Name	Endoscopic Instruments
Product Code and Classification Name	GEI; Electrosurgical cutting and Coagulation Devices and Accessories
Product Classification	21 CFR § 878.4400

Device Description

The ANTYLLOS® Endoscopic Tube Shaft Instruments for monopolar coagulation are a line of modular reusable endoscopic instruments with a HF-connection.
The instruments are made up of 3 separate components: an insulated handle, an insulated shaft and a working tip. The working tips come in several different styles, which can be used interchangeably. All components are reusable and disassemble for cleaning and sterilization. The instruments are 3 mm, 5 mm and 10 mm in diameter as well as 330 mm and 450 mm in length.

Intended Use

These Endoscopic Tube Shaft Instruments are used in laparoscopy and other minimally invasive procedures for cutting, dissecting, fixation and the taking of biopsy samples, depending on the design of the working tips. They are further intended to control bleeding by use of monopolar high-frequency electrical current.

Substantial Equivalence

The Endoscopic Tube Shaft Instruments are substantial equivalent to the predicate device of Aesculap, Richard Wolf, Karl Storz and others, since the basic features, design and intended uses are the same. The minor differences between the Antyllos Endoscopic Tube Shaft Instruments and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Performance Data

The devices conform to IEC 60601-2-2 and to the relevant provisions of European Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Antyllos Medizintechnik GmbH
c/o Mr. Harald Jung
Ing-Buero Jung
Unterer Winkel 3
78573 Wurmlingen,
Germany

Re: K010192
Trade Name: Endoscopic Tube Shaft Instruments
for Monopolar Coagulation
Regulatory Class: II
Product Code: GEI
Dated: January 12, 2001
Received: January 22, 2001

Dear Mr. Jung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010192

Device Name: Endoscopic Tube Shaft Instruments for Monopolar Coagulation

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010192

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)